SIEMENS

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: k131662

OCT 10 2013

1. **Submitter**

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Date Prepared:	August 30, 2013

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 ACTH Calibration Verification Material
Measurand:	Quality Control materials for IMMULITE® 2000 ACTH assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 ACTH assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name** — Elecsys ACTH CalCheck
   Predicate 510(k) No: K060585

4. **Device Description:** The Calibration Verification Material (CVM) contains one set of four vials, 3 mL each. LACCVM1 contains processed bovine protein matrix with preservatives. LACCVM2, LACCVM3 and LACCVM4 contain low, intermediate and high levels of ACTH respectively, in processed bovine protein based matrix with preservatives.

5. **Intended Use:** See Indications for Use Statement below
   Indication for Use: The IMMULITE® ACTH Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration and reportable range of the IMMULITE ACTH assay on the IMMULITE 2000 systems

Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	IMMULITE® 2000 Systems

6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 ACTH Calibration Verification Material (CVM) is substantially equivalent to the predicate device, Elecsys ACTH CalCheck, as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 ACTH CVM	**Predicate Device Elecsys ACTH CalCheck**
Intended Use	The IMMULITE® ACTH Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration and reportable range of the IMMULITE ACTH assay on the IMMULITE 2000 systems	For use in the verification of the calibration established by the Elecsys ACTH reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Analyte	ACTH	Same
Form	Lyophilized	Same
Traceability	Standardized gravimetrically	Same
DIFFERENCES		
Stability	Stable until the expiration date when stored frozen.	Stable until the expiration date when stored refrigerated.
Storage	-20°C	2-8°C
Matrix	Bovine protein based matrix with preservatives.	Buffered equine serum with preservatives.
Use	Single Use Only	Not for Single Use

7. **Non-Clinical Performance Testing**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the candidate device.

7.1 Stability Summary:

The stability study was conducted to validate the shelf life claim for the IMMULITE® 2000 ACTH Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platform throughout the established shelf life of the CVM. The IMMULITE® 2000 ACTH Calibration Verification Materials (CVMs) are stable up to 2 years when stored frozen at -20°C prior to opening.

7.1.1 Stability Protocol Summary:

The CVM study protocols are run as part of the calibrator stability testing. The stability CVMs and reference CVMs are run in duplicate (as a minimum) at the time points shown in Table 2 and the dose value determined from the reference calibrator curve.

Table 2: Stability Time Points:

CVM Level	Time-Points (Days)			
LACCVM1	1	182	548	730
LACCVM2	1	182	548	730
LACCVM3	1	182	548	730
LACCVM4	1	182	548	730

7.1.2 Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE 2000 ACTH Calibration Verification Material (CVM) consists of 2 parts. Part 1 consists of the Guideline Acceptance Criteria which requires the dose value stability CVM to fall between ±10% of the assigned dose. Part 2 consists of the Review Limits Acceptance Criteria which requires the dose value of the controls to be within 2SD of the control target value generated from the stability calibrator curve. If the result is not within the acceptable dose range of ±10%, then additional data review is performed using the part 2 acceptance criterion. The acceptance criteria is summarized in Table 3.

Table 3: Stability Acceptance Criteria for IMMULITE 2000 ACTH CVM

CVM Level	Assigned Dose (pg/mL)	Guideline Criteria % difference to assigned dose	Acceptable dose range (pg/mL)	Review Limits
LACCVM1	0.00	≤5.00	≤5.00	Not Applicable
LACCVM2	21.8	±10	19.62 – 23.98	Controls are within 2SD of target from stability calibrator curve
LACCVM3	238	±10	214.20 – 261.80	
LACCVM4	1214	±10	1092.6 – 1335.40	

7.2 Traceability:
The IMMULITE® 2000 ACTH Calibration Verification Materials are traceable to internal assigned reference calibrators prepared using ACTH antigen stock solution and are traceable to internal material which is gravimetrically prepared. The CVMs are manufactured using qualified materials and measurement procedures.

7.3 Value Assignment:
ACTH CVMs are 4 level materials which are subset of 8 level ACTH calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of ACTH reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The assigned reference calibrators are prepared using recombinant human ACTH 1-39 antigen stock and are traceable to internal material which has been gravimetrically prepared. Two levels of commercially available controls, and 40 patient samples (5 normal patients samples and 35 spiked normal patients samples) are used to validate CVM value assignments.

The CVMs are manufactured using qualified materials and measurement procedures. The CVMs were tested on 27 replicates in total comprised of nine runs and three replicates per run on eight systems and four different reagent kit lots. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples and controls using the assigned CVM values. The controls must fall within their target ranges

7.4 Expected Values/Reference Range:

Each CVM level was tested for a total of 27 replicates; 9 runs and 3 replicates per run. 5 different reagent kit lots and 8 different instruments were used to gain 27 replicates. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected values are provided in the IMMULITE® 2000 CVM Calibration verification Material lot-specific value card. The expected assay range is 5 - 1250 pg/mL. The target values in Table 4 can be considered as guidelines.

Table 4: Target Values

Analyte target levels	Level	Target Mean (pg/mL)	Standard Deviation (SD)	Guideline ±2SD Range (pg/mL)	
	1	0.00		0.00	≤5.00
	2	21.8	2.2	17.4	26.2
	3	238	22.5	193	283
	4	1214	91	1032	1396
Assay Range	5 -1250 pg/mL				

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® 2000 ACTH Calibration Verification Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys ACTH CalCheck. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, Elecsys ACTH CalCheck, The IMMULITE® 2000 ACTH Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 10, 2013

Siemens Healthcare Diagnostics, Inc.
c/o Garo Mimaryan
511 Benedict Ave
TARRYTOWN NY 10591-5097

Re: K131662
Trade/Device Name: Immulite 2000 ACTH Calibration Verification Material
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, reserved
Product Code: JJX
Dated: September 10, 2013
Received: September 11, 2013

Dear Garo Mimaryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131662

Device Name: IMMULITE®2000 ACTH Calibration Verification Material

Indication for Use:

The IMMULITE® ACTH Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration and reportable range of the IMMULITE ACTH assay on the IMMULITE 2000 systems

Prescription Use X	And/Or	Over the Counter Use_____
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k131662